

II. REMARKS

Formal Matters

Claims 1-22 are pending after entry of the amendments set forth herein.

Claims 12-16 were examined and were rejected. Claims 1-11 and 17-19 were withdrawn from consideration.

The paragraph beginning on page 11, line 5 of the specification is amended. Support for this amendment is found in claim 5 as filed.

Claim 12 is amended. The amendment to claim 12 was were made solely in the interest of expediting prosecution, and is not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendment to claim 12 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary location: page 6, lines 18-25. Accordingly, no new matter is added by this amendment.

Claims 20-22 are added. Support for new claims 20-22 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: claim 20: page 9, line 24 to page 10, line 21; claim 21: claim 4 as originally filed; claim 22: claim 5 as originally filed. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Objection to the Abstract

The Office Action objected to the Abstract as containing a file locator.

Applicants respectfully request entry of the amendment to the Abstract, as shown above, which amendment adequately addresses this objection.

Objection to the Specification

The Office Action stated that the trademark Crl:CD®IGS BR should be capitalized and accompanied by the generic terminology.

Applicants respectfully request entry of the amendment to the paragraph beginning on page 19, line 23 of the specification, as noted above.

Rejection under 35 U.S.C. §112, second paragraph

Claims 12 and 14-16 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Office Action stated that the recitation in claim 12 of “4-30 residues ... having at least one residue” is indefinite because it is not clear to what kind of residues the claim is referring.

Claim 12 is amended to recite “4-30 amino acid residues” and “having at least one amino acid residue.”

Applicants submit that the rejection of claims 12 and 14-16 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §103

Claims 12-16 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Reynolds (U.S. Patent No. 5,015,628) in view of Monier-Faugere et al. ((2000) Cecil Textbook of Medicine, 21st Ed., Vol. 166, Ch. 266, pages 1409-1414; “Monier-Faugere”).

The Office Action stated that Reynolds teaches a composition comprising a phosphopeptide from 5-30 amino acids, wherein the composition is in the form of a pharmaceutical composition. The Office Action stated that Reynolds does not teach a method of treating hyperphosphatemia. The Office Action stated that Reynolds states that the ability of the peptides to sequester calcium phosphate can be used in the treatment of various rarefying bone diseases. The Office Action stated that in view of the secondary reference, Monier-Faugere, one of ordinary skill in the art would understand that the phrase “treatment of various rarefying bone diseases” would include treatment of hyperphosphatemia. Applicants respectfully traverse the rejection.

There is no disclosure or suggestion in Reynolds of a method of treating hyperphosphatemia. There is no disclosure or suggestion in Reynolds of a method of treating hyperphosphatemia, the method comprising administering to an individual a therapeutically effective amount of a composition comprising a pharmaceutically acceptable excipient and a peptidic compound

characterized by (a) oral bioavailability, (b) 4 to 30 amino acid residues, and (c) having at least one amino acid residue which is phosphorylated or which is phosphorylatable *in vivo* or *in vitro*.

As the Office Action acknowledged, Reynolds does not disclose a method of treating hyperphosphatemia. Reynolds relates to a method of treating dental diseases such as caries, gingivitis, and periodontal diseases, rarefying bone diseases such as osteoporosis and osteomalacia, and diseases relating to malabsorption of minerals. Reynolds, column 1, lines 28-33. There is no discussion in Reynolds of a method of treating hyperphosphatemia.

Reynolds states that the peptides discussed therein accumulate in plaque and enamel. Reynolds, column 8, lines 8-10. Accumulation in plaque and enamel is not a reduction in serum phosphate levels. Accordingly, Reynolds cannot render the instant claims obvious.

Reynolds states that the peptides increase absorption of calcium, phosphate, and iron in the gut. Reynolds, column 8, lines 29-31. An increase in absorption of phosphate from the gut would be expected to increase serum phosphate levels, not to decrease serum phosphate levels, as presently claimed. Thus, Reynolds appears to teach the **opposite** of the method as claimed. Accordingly, Reynolds cannot render the instant claims obvious.

Monier-Faugere does not cure the deficiency of Reynolds. Monier-Faugere merely discusses renal osteodystrophy, and does not lead to the conclusion, as stated in the Office Action, that the phrase "treatment of various rarefying bone diseases" would include treatment of hyperphosphatemia. Thus, there is nothing in Monier-Faugere that would motivate a person of ordinary skill in the art to combine the teachings of Monier-Faugere with those of Reynolds. Even if one did combine the teachings of Monier-Faugere with the teachings of Reynolds, one would not arrive at the instant method as claimed.

Applicants submit that the rejection of claims 12-16 under 35 U.S.C. §103 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

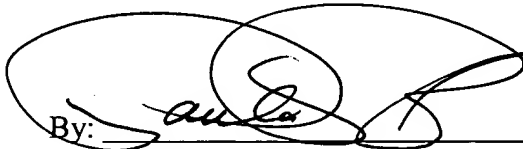
III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BEAR004.

Respectfully submitted,
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Date: Oct. 17, 2003

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